- Filing application for specific licenses. (1) WAC 246-235-010 Applications for specific licenses must be filed on department form RHF-1.
- (2) The department may at any time after the filing of the origiapplication, and before the expiration of the license, require further statements in order to enable the department to determine whether the application should be granted or denied or whether a license should be modified or revoked.
- (3) Each application must be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's behalf.

 (4) An application for a license may include a request for a li-
- cense authorizing one or more activities.
- (5) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the department provided such references are clear and specific.
- (6) Except as provided in (c), (d), and (e) of this subsection, an application for a specific license to use radioactive materials in the form of a sealed source or in a device that contains the sealed
- (a) Identify the source or device by manufacturer and model number; or
 - (b) Be registered with the NRC under 10 C.F.R. 32.210; or
- (c) For sources or devices manufactured before October 23, 2012, that are not registered with the NRC((, provide)) or an agreement state, and for which the applicant is unable to provide all categories of information specified in WAC 246-235-108(3), the application must include:
- (i) All available information identified in WAC 246-235-108(3) concerning the source, and, if applicable, the device;
- (ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use((, relevant operational safety history)) and associated operating experience, and the results of the most recent leak test.
- (d) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 C.F.R. 32.210 or this section, the applicant may supply only the manufacturer, model number, and radionuclide and quantity.
- (e) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used, and the conditions under which they will be used, in lieu of identifying each sealed source and device.
- (7) Applications and documents submitted to the department may be made available for public inspection except that the department may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

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NEW SECTION

- WAC 246-235-082 Special requirements for issuance of a specific license to initially transfer source material. In addition to the requirements set forth in WAC 246-235-020, an application for a specific license to initially transfer source material for use under 10 C.F.R. 40.22 or WAC 246-233-010 or equivalent regulations of an agreement state will be approved if:
- (1) The applicant satisfies the general requirements specified in WAC 246-235-020; and
- (2) The applicant submits adequate information about, and the department approves, the methods to be used for quality control, labeling, and providing safety instructions to recipients.

NEW SECTION

- WAC 246-235-083 Conditions of licenses to initially transfer source material for use under general license—Quality control, labeling, safety instructions, and reports and records. (1) Each person licensed under WAC 246-235-082 shall label the immediate container of each quantity of source material with the type and quantity of source material and the words "radioactive material."
- (2) Each person licensed under WAC 246-235-082 shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.
- (3) Each person licensed under WAC 246-235-082 shall provide the information specified in this section to each person to whom source material is transferred for use under WAC 246-233-010, 10 C.F.R. 40.22, or equivalent provisions in agreement state regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:
- (a) A copy of 10 C.F.R. 40.22 and 10 C.F.R. 40.51, or WAC 246-232-080 and 246-233-010, or equivalent agreement state regulations.
- (b) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.
- (4) Each person licensed under this section shall report transfers as follows:
- (a) File a report with the director, Office of Radiation Protection, Radioactive Materials Section, P.O. Box 47827, Olympia, WA 98504. The report shall include the following information:
- (i) The name, address, and license number of the person who transferred the source material;
- (ii) For each general licensee under these rules, 10 C.F.R. 40.22, or equivalent agreement state regulations, to whom greater than 50 grams (0.11 lbs.) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

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- (iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.
- (b) File a report with each responsible agreement state agency that identifies all persons, operating under provisions of 10 C.F.R. 40.22 or equivalent regulations of the department or an agreement state, to whom greater than 50 grams (0.11 lbs.) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state being reported to:
- (i) The name, address, and license number of the person who transferred the source material;
- (ii) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and
- (iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the agreement state.
- (c) Submit each report by January 31st of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 10 C.F.R. 40.22 or equivalent department rules or agreement state regulations during the current period, a report shall be submitted to the department so indicating. If no transfers have been made to general licensees in a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon request by the agency.
- (5) Each person licensed under 10 C.F.R. 40.54 or equivalent department or agreement state regulations shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of one year after the event is included in a report to the department, NRC, or to an agreement state agency.

AMENDATORY SECTION (Amending WSR 15-06-015, filed 2/23/15, effective 3/26/15)

WAC 246-235-093 Manufacture, assembly or distribution of devices under general license. (1) An application for a specific license to manufacture or initially transfer or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under WAC 246-233-020 or equivalent regulations of the NRC or an agreement state will be approved if:

- (a) The applicant satisfies the general requirements of WAC 246-235-020;
- (b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
- (i) The device can be safely operated by persons not having training in radiological protection;

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- (ii) Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of ten percent of the limits specified in the table in WAC 246-221-010(1); and
- (iii) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye . . . 15 centigray (15 rem) Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter 200 centigray (200 rem) Other organs 50 centigray (50 rem)

- (c) Each device bears a durable, legible, clearly visible label or labels approved by the department, which contain in a clearly identified and separate statement:
- (i) Instructions and precautions necessary to assure safe installation, operation and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);
- (ii) The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by nuclide, quantity of radioactivity, and date of determination of the quantity; and
- (iii) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:
- (A) The receipt, possession, use and transfer of this device, Model , Serial No. Note*, are subject to a general license or the equivalent, and the regulations of the NRC or a state with which the NRC has entered into an agreement for the exercise of regulatory authority. This label must be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

(Name of manufacturer or distributor)*

(B) The receipt, possession, use and transfer of this device, Model , Serial No. Note*, are subject to a general license or the equivalent, and the rules of an agreement state. This label must be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

(Name of manufacturer or distributor)*

*Note: The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(d) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the nuclide and quantity, the words, "CAUTION - RADIOACTIVE MATERI-

AL," the radiation symbol described in WAC 246-221-120, and the name of the manufacturer or initial distributor;

- (e) Each device meeting the criteria of WAC 246-233-020 (3)(k), bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "CAUTION RADIOACTIVE MATERIAL," and, if practicable, the radiation symbol described in WAC 246-221-120 \underline{i}
- (f) The device has been registered in the sealed source and device registry.
- (2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the department will consider information which includes, but is not limited to:
 - (a) Primary containment (source capsule);
 - (b) Protection of primary containment;
 - (c) Method of sealing containment;
 - (d) Containment construction materials;
 - (e) Form of contained radioactive material;
 - (f) Maximum temperature withstood during prototype tests;
 - (g) Maximum pressure withstood during prototype tests;
 - (h) Maximum quantity of contained radioactive material;
 - (i) Radiotoxicity of contained radioactive material; and
- (j) Operating experience with identical devices or similarly designed and constructed devices.
- (3) In the event the applicant desires that the general licensee under WAC 246-233-020, or under equivalent regulations of the NRC or an agreement state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant must include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information must demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive in one year a radiation dose in excess of ten percent of the limits specified in the table in WAC 246-221-010(1).
- (4) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to generally licensed persons must provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. If transfer is through an intermediate person, the information much also be provided to the intended user before initial transfer to the intermediate person.

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- (a) If a device containing radioactive material is to be transferred for use under the general license contained in WAC 246-233-020, the required information must include:
- (i) A copy of the general license contained in WAC 246-233-020. If WAC 246-233-020 (3)(b), (c), and (d) or (k) do not apply, those subsections may be omitted;
- (ii) A copy of WAC 246-232-050, 246-221-230, 246-221-240, and 246-221-250;
- (iii) A list of the services that can only be performed by a specific licensee; and
- (iv) Information on acceptable disposal options including estimated costs of disposal; and
- (v) An indication that the NRC's policy is to issue high civil penalties for improper disposal.
- (b) If a device containing radioactive material is to be transferred for use in another jurisdiction under a general license equivalent to WAC 246-233-020, the required information must include:
- (i) A copy of the appropriate NRC or an agreement state's regulations, equivalent to WAC 246-233-020, 246-232-050, 246-221-230, and 246-221-240, 246-221-250. Ιf WAC 246-233-020, a copy of 246-232-050, 246-221-230, 246-221-240, and 246-221-250 is provided to a prospective general licensee in lieu of the NRC's or the agreement state's regulations, it must be accompanied by a note explaining that the use of the device is regulated by the NRC or the agreement state. If certain subsections do not apply to the particular device, those subsections may be omitted;
- (ii) A list of the services that can only be performed by a specific licensee;
- (iii) Information on acceptable disposal options including estimated cost of disposal;
- (iv) The name or title, address, and phone number of the contact at the appropriate NRC or an agreement state regulatory agency from which additional information may be obtained; and
- (v) An indication that NRC policy is to issue high civil penalties for improper disposal;
- (c) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to persons generally licensed under WAC 246-233-020 must report to the department all transfers of devices to persons for use under the general license in WAC 246-233-020 and all receipts of devices from persons licensed under WAC 246-233-020.
- (i) Each report must be clear and legible and contain all of the data required. The required information for transfers to general licensees includes:
- (A) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee must be included with information on the actual location of use;
- (B) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
 - (C) The date of transfer;
- (D) The manufacturer or initial transferor, the type, model number and serial number of the device transferred; and
- (E) The source serial(s), nuclide(s), activity, and date(s) of original activity of radioactive material contained in the device.

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- (ii) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, clearly identify and designate each intermediate person by name, address, contact, and relationship to the intended user.
- (iii) For devices received from a general licensee under WAC 246-233-020, the report must include:
 - (A) The identity of the general licensee by name and address;
- (B) The type, model number, and serial number of the device received; and the source serial(s), nuclide(s), activity, and date(s) of original activity of radioactive material contained in the device;
 - (C) The date of receipt; and
- (D) In the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
- (iv) If the licensee makes changes to a device possessed by a person generally licensed under WAC 246-233-020, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.
- (v) If no transfers have been made to or from persons generally licensed under WAC 246-233-020 during the reporting period, the report must so indicate.
- (vi) The report must cover each calendar quarter, must clearly indicate the period covered by the report, and must be filed within thirty days of the end of the calendar quarter.
- (vii) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
 - (d) Reports to NRC or an agreement state regulatory agency.
- (i) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to persons generally licensed under the NRC's regulations equivalent to WAC 246-233-020 must report to the NRC all transfers of devices to persons for use under a general license equivalent to WAC 246-233-020 and all receipts of devices from persons licensed under regulations equivalent to WAC 246-233-020.
- (ii) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to persons generally licensed under an agreement state's regulations equivalent to WAC 246-233-020 must report to the agreement state's regulatory authority all transfers of devices to persons for use under a general license equivalent to WAC 246-233-020 and all receipts of devices from persons licensed under regulations equivalent to WAC 243-233-020.
- (iii) Such report must be clear and legible and contain all of the data required. The required information for transfers to general licenses must include:
- (A) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee must be submitted along with information on the actual location of use;
- (B) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
 - (C) The date of transfer;
- (D) The type, model number and serial number of the device transferred; and

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- (E) The quantity and type of radioactive material contained in the device.
- (iv) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).
- (v) For devices received from persons generally licensed under NRC's or an agreement state's regulations equivalent to WAC 246-233-020, the report must include:
 - (A) The identity of the general licensee by name and address;
- (B) The type, model number, and serial number of the device received;
 - (C) The date of receipt; and
- (D) In the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
- (vi) If the licensee makes changes to a device possessed by a person generally licensed under NRC's or an agreement state's regulations equivalent to WAC 246-233-020, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.
- (vii) The report must cover each calendar quarter, must be filed within thirty days of the end of the calendar quarter, and must clearly indicate the period covered by the report.
- (viii) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
- (\mbox{ix}) If no transfers have been made to or from NRC licensees during the reporting period, this information must be reported to the NRC.
- (x) If no transfers have been made to or from general licensees within an agreement state during the reporting period, this information must be reported to the responsible agreement state agency upon request of the agency.
- (e) The person shall maintain all information and keep records concerning transfers and receipts of devices that support the reports required by this section. Records required by this section must be maintained for a period of three years following the date of the recorded event.
- (f) If a notification of bankruptcy has been made under WAC 246-233-050 or the license is to be terminated, each person licensed under this section shall provide, upon request, to the department, the NRC or an agreement state, records of final disposition required under $((this\ subsection\ (4)))(e)$ of this subsection.

<u>AMENDATORY SECTION</u> (Amending WSR 04-04-055, filed 1/30/04, effective 3/1/04)

WAC 246-235-095 Manufacture, assembly, or distribution of luminous safety devices, certain calibration sources or ice detectors under general license. (1) Special requirements for the manufacture, assembly or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble ((er)),

repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft for distribution to persons generally licensed under WAC 246-233-025 will be approved subject to the following conditions:

- (a) The applicant satisfies the general requirements specified in WAC 246-235-020; and
- (b) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, and $32.56((\frac{32.101}{20.100}))$ of 10 C.F.R. Part 32 or their equivalent.
- (2) Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under WAC 246-233-035. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under WAC 246-233-035 will be approved subject to the following conditions:
- (a) The applicant satisfies the general requirement of WAC 246-235-020; and
- (3) Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under WAC 246-233-030 will be approved subject to the following conditions:
- (a) The applicant satisfies the general requirements of WAC 246-235-020; and
- (b) The criteria of Sections 32.61((-7)) and 32.62((-7)) of 10 C.F.R. Part 32 are met.

AMENDATORY SECTION (Amending WSR 13-24-025, filed 11/22/13, effective 12/23/13)

WAC 246-235-102 Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under chapter 246-240 WAC for use as a calibration, transmission, or reference source or for the uses listed in WAC 246-240-251, 246-240-301, and 246-240-351 will be approved if:

- (1) The applicant satisfies the general requirements in WAC 246-235-020;
- (2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
- (a) The radioactive material contained, its chemical and physical form and amount;
 - (b) Details of design and construction of the source or device;
- (c) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;
- (d) For devices containing radioactive material, the radiation profile of a prototype device;

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- (e) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;
 - (f) Procedures and standards for calibrating sources and devices;
- (g) Legend and methods for labeling sources and devices as to their radioactive content; and
- (h) Instructions for handling and storing the source or device from the radiation safety standpoint, these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device: Provided that instructions which are too lengthy for the label may be summarized on the label and printed in detail on a brochure which is referenced on the label.
- (3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the named source or device is licensed by the department for distribution to persons licensed under chapter 246-240 WAC or under equivalent regulations of the NRC or an agreement state: Provided that the labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source((\cdot,\cdot)):
- (4) The source or device has been registered in the sealed source and device registry.
- (5) If the applicant desires that the source or device be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.
- $((\frac{5}{1}))$ In determining the acceptable interval for test of leakage of radioactive material, the department will consider information that includes, but is not limited to:
 - (a) Primary containment (source capsule);
 - (b) Protection of primary containment;
 - (c) Method of sealing containment;
 - (d) Containment construction materials;
 - (e) Form of contained radioactive material;
 - (f) Maximum temperature withstood during prototype tests;
 - (g) Maximum pressure withstood during prototype tests;
 - (h) Maximum quantity of contained radioactive material;
 - (i) Radiotoxicity of contained radioactive material; and
- (j) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

NEW SECTION

WAC 246-235-108 Sealed source and device registration and inactivation. (1) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the department or NRC for evaluation of radiation safety information about its product and for its registration.

- (2) Request for review must be sent to the department or to NRC's office of nuclear material safety and safeguards, ATTN: SSDR, by an appropriate method listed in 10 C.F.R. 30.6(a).
- (3) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.
- (4) The department normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the department formulates reasonable standards and criteria with the help of the manufacturer or distributor. The department shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. 10 C.F.R. 32 Subpart A includes specific criteria that apply to certain exempt products, Subpart B includes specific criteria applicable to certain generally licensed devices, and Subpart C includes specific provisions that apply to certain specifically licensed items.
- (5) After completion of the evaluation, the department issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.
- (6) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:
- (a) The statements and representations, including quality control program, contained in the request; and
 - (b) The provisions of the registration certificate.
- (7) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:
 - (a) Calibration and reference sources containing no more than:
- (i) 37 megabecquerels (one millicurie) for beta or gamma emitting radionuclides; or
- (ii) 0.37 megabecquerels (ten microcuries), for alpha emitting radionuclides; or
- (b) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses and:
- (i) The intended recipients are licensed under WAC 246-235-090 of this chapter, 10 C.F.R. 33, or comparable provisions of an agreement state;

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- (ii) The recipients are authorized for research and development; or
- (iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 gigabecquerels (20 curies) of tritium (H-3) or 7.4 gigabecquerels (200 millicuries) of any other radionuclide.
- (8) After the certificate is issued, the department may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the department will complete its evaluation in accordance with criteria specified in this section. The department may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.
- (9)(a) A certificate holder who no longer manufactures or initially transfers any of the sealed sources or devices covered by a particular certificate issued by the department or NRC shall request inactivation of the registration certificate from the issuing regulatory authority. Such a request must be made to the department, or (as appropriate) to NRC's office of nuclear material safety and safeguards, ATTN: SSDR by an appropriate method listed in 10 C.F.R. 30.6(a) and must normally be made no later than two years after initial distribution of all of the sources or devices covered by the certificate has ceased. However if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within ninety days of this determination and briefly describe the circumstances of the delay.
- (b) If a distribution license is to be terminated in accordance with chapters 246-232, 246-233, and 246-235 WAC, the licensee shall request inactivation of its registration certificates associated with that distribution license before the department will terminate the license. Such a request for inactivation of certificates must indicate that the license is being terminated and include the associated specific license number.
- (c) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.